

## **Emergency Exemption for Transform® WG Insecticide (sulfoxaflor) to control the sugarcane aphid, *Melanaphis sacchari*, in sorghum.**

**Type of Emergency Exemption for Louisiana:** specific exemption under FIFRA Section 18; January 15, 2016.

This is an application for a specific exemption to authorize the use of Sulfoxaflor (Transform® WG Insecticide EPA Reg. No. 62719-625) to control the sugarcane aphid (SA), *Melanaphis sacchari*, in sorghum. The following information is submitted in the format indicated in the proposed rules for Chapter 1, Title 40 CFR, Part 166.

### **SECTION 166.20(a)(1): IDENTITY OF CONTACT PERSONS**

- i. The following contact person is available to answer regulatory questions regarding the Section 18 emergency exemption:

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- ii. The following qualified experts are also available to answer questions:

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### **SECTION 166.20(a)(2): DESCRIPTION OF THE PESTICIDE REQUESTED**

i. **Common Chemical Name (Active Ingredient):** Sulfoxaflor

Brand/Trade Name and EPA Reg. No.: Transform® WG Insecticide, EPA  
Reg. No. 62719-625 (Attachment 2)

Formulation: Active Ingredient 50%

### **SECTION 166.20(a)(3): DESCRIPTION OF THE PROPOSED USE**

i. **Sites to be Treated:**

Sorghum fields (grain and forage) with the sugarcane aphid (SA), *Melanaphis sacchari* located statewide are proposed to be treated.

ii. **Method of Application:**

The proposed method of application will be a foliar application when large SA populations are present.

iii. **Rate of Application:**

The proposed rate of application is 0.75 – 1.5 oz of Transform® WG/acre (0.023 – 0.047 lb ai/acre).

iv. **Maximum Number of Applications:**

The proposed maximum number of applications is 2 applications per year (maximum of 3 oz/acre (0.09 lb ai/acre) per year.

v. **Total Acreage to be Treated:**

For the 2015 growing season, Dr. Kerns estimated that 85,000 acres of sorghum was cultivated in Louisiana. In addition, Dr. Kerns estimated the acreage planted in sorghum for grain and forage in Louisiana for 2016 should not exceed 180,000 acres.

vi. **Total Amount of Pesticide to be used:** In 2015, Dr. Kerns estimated the SA was present on 70% of grain sorghum acres grown in Louisiana.

Therefore, if an estimated maximum SA infestation (100% infestation on 180,000 acres of sorghum) were treated at the maximum rate for the year of 3 oz./acre (0.09 lb a.i./acre) then 33,750 lbs of Transform® WG or 16,200 pounds of active ingredient would be used in 2016.

**vii. Restrictions and Requirements:**

- Pre-harvest Interval: Do not apply within 14 days of grain or straw harvest or within 7 days of grazing for forage, fodder, or hay harvest.
- A restricted entry interval (REI) of 24 hours must be observed.
- Do not make more than two applications per acre per year.
- Minimum Treatment Interval: Do not make applications less than 14 days apart.
- Do not apply more than a total of 3.0 oz of Transform WG (0.09 lb ai of sulfoxaflor) per acre per year.

**viii. Duration of the Proposed Use:**

The duration of the proposed use would extend from spring through late summer.

**ix. Earliest Possible Harvest Date:**

Based on USDA/NASS statistics (Attachment 3), sorghum planting dates in Louisiana range, on average, from April 11 – May 15. Louisiana harvest dates, on average, range from August 16 – September 10. The usual beginning harvest date is August 7.

## **SECTION 166.20(a)(4): ALTERNATIVE METHODS OF CONTROL**

**i. Registered Alternative Pesticides**

The active ingredients - imidacloprid, clothianidin, thiamethoxam, and terbufos are registered only as seed treatments and in-furrow applications (these products are discussed in the immediate following section). Other registered products we have tested includes chlorpyrifos, dimethoate, and malathion. Dimethoate and malathion provided only 20-50% control of SA in sorghum. Chlorpyrifos at the top label rate of 1 qt/ac, does provide acceptable, but inconsistent, control. However, chlorpyrifos is harsh on beneficial insects and SCA resurgence may occur fairly quickly. Lower rates of chlorpyrifos offer only suppression. Also, the PHI (pre harvest interval) for products containing chlorpyrifos and dimethoate range from 28-60 days, thus preventing their legal use for late season SCA infestations which are common in Louisiana.

**ii. Insecticide Seed Treatments**

Among the insecticide seed treatments, imidacloprid, clothianidin and thiamethoxam have proven useful in preventing early-season colonization of sorghum by SCA, this activity only lasts 24-40 days depending on weather and soil type. Thus, seed treatments have proven to be useful tools for managing SCA in sorghum, particularly late-planted sorghum. However, they do not offer season-long control.

### **iii. Alternatives to Transform and Resistance Concerns**

Heavy reliance on a single insecticide mode of action is not a sustainable pest management solution. Based on data collected in 2013-15, other than Sivanto (flupyrifurone), currently labeled insecticides are not highly effective towards sugarcane aphid and/or have prohibitively long PHIs. During 2014-15, we conducted bioassays to characterize the susceptibility of SCA to sulfoxaflor and flupyrifurone (2015 only). Between 2014 and 2015 we observed a slight shift towards reduced susceptibility of sulfoxaflor to SCA. Additionally, LC50s of sulfoxaflor during both years was quite variable. These types of data throw up the proverbial “red flag” that this particular active ingredient may be at greater risk of having resistance develop. Additionally, our tests investigating the residual activity of sulfoxaflor and flupyrifurone demonstrate that whereas sulfoxaflor places selection pressure on SCA for a relatively short period of time (10 days). Longer residual insecticides are general at greater risk of having resistance develop as well. Thus, we have legitimate data driven concerns for SCA developing resistance to both sulfoxaflor and flupyrifurone. Additionally, Sivanto has a 28 day PHI which renders it useless near harvest. It is also my understanding that many parts of the U.S., with SCA infestation problems, did not have access to Sivanto due to supply problems. Other non-labelled insecticides that have proven effective towards SCA in plot trials include: acetamiprid and thiamethoxam. However, the ecological fit of these insecticides as an alternative to sulfoxaflor is not certain.

### **iv. Pollinator Concerns**

In Louisiana we have developed a pollinator protection plan that we hope will aid in enhancing protection of pollinators and fostering communication among farmers, pesticide applicators, landowners and bee keepers. With the recent court ruling that resulted in the cancellation of the Section 3 label for sulfoxaflor, there is justification for further evaluation of alternative insecticides with pollinator protection considerations. Based on toxicity to honey bees, there are not many alternatives to Transform available for SCA. Centric (thiamethoxam) is efficacious towards SCA, but is much more toxic to honey bees than Transform. Another potential alternative is acetamiprid. Our tests suggest that at 3.3.5oz/ac, Strafer (acetamiprid) is effective towards SCA, yet is much safer towards bees. However, we have been informed that there may be some avian and aquatic non-vertebrate toxicity concerns with this active ingredient.

### **v. Action Threshold**

In 2014 and 2015, a joint project between researchers in Texas and Louisiana was conducted to establish an economic threshold. The tests were identical and were comprised of one susceptible and one resistant sorghum hybrid (not commercial). These entries were treated at various aphid densities of 0, 50, 100, 250 and 500 per leaf. Aphid numbers were collected and yields recorded. Regression analyses were used to determine an aphid density to yield relationship. Both sites had differences in yields for the susceptible hybrid and no yield response for the resistant hybrid. Based on regression models, cost associated with control, yield potential and the value of sorghum, we were able to compute economic injury levels in aphids per leaf. The economic threshold is set lower than the injury level so we reduced the value by 30%. Based on these values, we determined that the threshold should be 50.125 aphids per leaf. However, we also need to take into account the clumped distribution aphids possess and the lag time from when the threshold is met to when the grower can actually make an

application. Although a field may be relatively free of severe aphid infestations, “hot spots” in the field with high populations will suffer yield loss and stunting. The stunting is highly significant since these areas will be out of physiological synchrony with the majority of the crop and subject to severe injury from sorghum midge. Thus, until we generate more data, we are setting our threshold at 20% of leaves with 50 or more aphids per leaf. This threshold is for pre-boot to milk stage sorghum only. The threshold for soft dough stage and beyond is very likely lower.

#### **vi. Resistant Sorghum Hybrids**

Host plant resistance towards SCA is a viable long term goal for managing SCA. In 2015 we made a concerted effort to evaluate and identify sorghum hybrids that may offer resistance to SCA. Our data suggests that a number of hybrids offer some degree of protection from SCA infestation and/or injury. However, this resistance is not complete and treatable SCA populations may still develop, especially near harvest. Therefore, even though SCA resistant sorghum hybrids may be planted, and may prove highly beneficial, the need may still arise to treat those hybrids for SCA.

#### **vii. Integrated Approach**

Although I will not go into detail in the section, managing sugarcane aphid will require an integrated approach to be successful. There are a number of factors that play into this approach:

1. Hybrid selection
  - a. Identifying those with resistance/tolerance
  - b. Less compact hybrids to avoid sticky leaf tissue at harvest
2. Seed treatments
3. Proper insecticide selection
  - a. Efficacy
  - b. PHIs
  - c. Potential impact on non-targets
  - d. Avoid adjuvants
  - e. Resistance management
4. Proper insecticide application
  - a. Use high volumes
  - b. Use ground applications when possible
  - c. Avoid mixing with pyrethroids
5. Preserving natural enemies
  - a. Avoid broad spectrum insecticides when possible
    - i. Especially pyrethroids
6. Treating based on a proven threshold
  - a. Treat at 20% of leaves with 50 or more aphids per leaf.
7. Harvest
  - a. Insure low aphids at harvesting
    - i. Means being aggressive at 14 days before harvest
    - ii. Be prepared for all remaining aphids to move into the head
    - iii. Be prepared for sticky leaves

## **SECTION 166.20(a)(5): EFFICACY OF USE PROPOSED UNDER SECTION 18**

In 2013, after receiving calls of damaging aphid infestations on sorghum in Louisiana, Dr. David Kerns made a quick assessment of the situation and the pest was identified as SCA. This was a new pest of sorghum and Dr. Kerns had received information that the attempts at control using the currently available products were not effective. Therefore, Dr. Kerns quickly organized insecticide trials in Louisiana to measure the efficacy of products for control of the SCA infestations on sorghum in Louisiana. Data showed that sulfoxaflor, Transform® WG, at 1 oz/acre provided greater than 90% control of *Melanaphis* sp. whereas other currently available products, containing the actives - chlorpyrifos, malathion, dimethoate, and acetamiprid, provided no greater than 50% control.

In 2014 the Environmental Protection Agency granted a Section 18 registration for the use of Transform (sulfoxaflor). This registration proved highly successful and epitomizes the reasoning for Section 18 registration and the cooperation among federal, state and local agencies. Transform also has a 14 day PHI which allows its use closer to harvest when aphids are often severe. In addition to Transform, there was a Section 3 registration granted for Sivanto (flupyradifurone) in 2015. Both of these products are efficacious towards SCA. However, the 21 day PHI associated with Sivanto prevents its use post bloom when SCA infestations are common. It is imperative that sorghum growers have an efficacious insecticide available within 21 days of harvest. Transform fits this window with a 14 day PHI. Additionally, we are concerned that heavy reliance on a single mode of action will result in selecting SCA resistant to that insecticide. We need to be able to rotate insecticide chemistries to help prevent resistance from developing.

### **Impact on yield and harvest**

In tests LSU and others conducted in 2014 and 2015, positive yield responses were commonly noted for sugarcane aphid control in sorghum. On one such test treated at bloom, 100 sugarcane aphids per leaf were demonstrated to result in 340 lbs of grain yield loss. It is not uncommon for aphids to number 1000's per leaf. In another test, 100 aphids resulted in 578 lbs of grain loss. In addition to bloom, yield loss due to aphid infestations has also been demonstrated at the seedling stage, pre-boot, boot, milk and soft dough stages. Although direct yield loss is not known to occur at hard dough stage, harvest efficiency issues where aphids and sticky leaves clog the combine have resulted in as much as 50% grain loss. Because of this loss at harvest, growers ideally could benefit from an insecticide that can be utilized at harvest with a 7 day or less PHI, but definitely no longer than 14 days.

## **SECTION 166.20(a)(6): EXPECTED RESIDUES FOR FOOD USES**

### **Acute Assessment**

Food consumption information from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and maximum residues from field trials rather than tolerance level

residue estimates were used. It was assumed that 100% of crops covered by the registration request are treated and maximum residue levels from field trials were used.

Drinking water. Two scenarios were modeled, use of sulfoxaflor on non-aquatic row and orchard crops and use of sulfoxaflor on watercress. For the non-aquatic crop scenario, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for acute exposures are 26.4 ppb for surface water and 69.2 ppb for ground water. For chronic exposures, EDWCs are 13.5 ppb for surface water and 69.2 ppb for ground water. For chronic exposures for cancer assessments, EDWCs are 9.3 ppb for surface water and 69.2 ppb for ground water. For the watercress scenario, the EDWCs for surface water are 91.3 ppb after one application, 182.5 ppb after two applications and 273.8 ppb after three applications.

Dietary risk estimates using both sets of EDWCs are below levels of concern. The non-aquatic-crop EDWCs are more representative of the expected exposure profile for the majority of the population. Also, water concentration values are adjusted to take into account the source of the water; the relative amounts of parent sulfoxaflor, X11719474, and X11519540; and the relative liver toxicity of the metabolites as compared to the parent compound.

For acute dietary risk assessment of the general population, the groundwater EDWC is greater than the surface water EDWC and was used in the assessment. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540 (totaling 69.2 ppb). Parent sulfoxaflor does not occur in groundwater. The regulatory toxicological endpoint is based on neurotoxicity.

For acute dietary risk assessment of females 13-49, the regulatory endpoint is attributable only to the parent compound; therefore, the surface water EDWC of 9.4 ppb was used for this assessment.

A tolerance of 0.3 ppm for sulfoxaflor on grain sorghum has been established. There is no expectation of residues of sulfoxaflor and its metabolites in animal commodities as a result of the proposed use on sorghum. Thus, animal feeding studies are not needed, and tolerances need not be established for meat, milk, poultry, and eggs.

Drinking water exposures are the driver in the dietary assessment accounting for 100% of the exposures. Exposures through food (sorghum grain and syrup) are zero.

The acute dietary exposure from food and water to sulfoxaflor is 16% of the aPAD for children 1-2 years old and females 13-49 years old, the population groups receiving the greatest exposure.

### **Chronic Assessment**

The same refinements as those used for the acute exposure assessment were used, with two exceptions: (1) average residue levels from crop field trials were used rather than maximum values and (2) average residues from feeding studies, rather than maximum values, were used to derive residue estimates for livestock commodities. It was assumed that 100% of crops are treated and average residue levels from field trials were used.

For chronic dietary risk assessment, the toxicological endpoint is liver effects, for which it is possible to account for the relative toxicities of X11719474 and X11519540 as compared to sulfoxaflor. The groundwater EDWC is greater than the surface water EDWC. The residue profile in groundwater is

60.9 ppb X11719474 and 8.3 ppb X11519540. Adjusting for the relative toxicity results in 18.3 ppb equivalents of X11719474 and 83 ppb X11519540 (totaling 101.3 ppb). The adjusted groundwater EDWC is greater than the surface water EDWC (9.3 ppb) and was used to assess the chronic dietary exposure scenario.

The maximum dietary residue intake via consumption of sorghum commodities would be only a small portion of the RfD (<0.001%) and therefore, should not cause any additional risk to humans via chronic dietary exposure. Consumption of sorghum by sensitive sub-populations such as children and non-nursing infants is essentially zero. Thus, the risk of these subpopulations to chronic dietary exposure to sulfoxaflor used on grain sorghum would be insignificant.

The major contributor to the risk was water (100%). There was no contribution from grain sorghum to the dietary exposure. All other populations under the chronic assessment show risk estimates that are below levels of concern.

Chronic exposure to sulfoxaflor from food and water is 18% of the cPAD for infants, the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

Short-term risk. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed, no further assessment of short-term risk is necessary, the chronic dietary risk assessment for evaluating short-term risk for sulfoxaflor is sufficient.

Intermediate-term risk. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no residential exposure and chronic dietary exposure has already been assessed, no further assessment of intermediate-term risk is necessary.

Cumulative effects. Sulfoxaflor does not share a common mechanism of toxicity with any other substances, and does not produce a toxic metabolite produced by other substances. Thus, sulfoxaflor does not have a common mechanism of toxicity with other substances.

Cancer. A nonlinear RfD approach is appropriate for assessing cancer risk to sulfoxaflor. This approach will account for all chronic toxicity, including carcinogenicity that could result from exposure to sulfoxaflor. Chronic dietary risk estimates are below levels of concern; therefore, cancer risk is also below levels of concern.

There is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflor as used in this emergency exemption request.

*The content in the above Section 166.20(a)(6): "Expected Residues For Food Uses" was prepared by Michael Hare, Ph.D., Texas Department of Agriculture.*

## **Human Health**

### Toxicological Profile

Sulfoxaflor is a member of a new class of insecticides, the sulfoximines. It is an activator of the nicotinic acetylcholine receptor (nAChR) in insects and, to a lesser degree, mammals. The nervous system and liver are the target organs, resulting in developmental toxicity and hepatotoxicity.

Developmental toxicity was observed in rats only. Sulfoxaflor produced skeletal abnormalities likely resulting from skeletal muscle contraction due to activation of the skeletal muscle nAChR in utero. Contraction of the diaphragm, also related to skeletal muscle nAChR activation, prevented normal breathing in neonates and increased mortality. The skeletal abnormalities occurred at high doses while decreased neonatal survival occurred at slightly lower levels.

Sulfoxaflor and its major metabolites produced liver weight and enzyme changes, and tumors in subchronic, chronic and short-term studies. Hepatotoxicity occurred at lower doses in long-term studies compared to short-term studies.

Reproductive effects included an increase in Leydig cell tumors which were not treatment related due to the lack of dose response, the lack of statistical significance for the combined tumors, and the high background rates for this tumor type in F344 rats. The primary effects on male reproductive organs are secondary to the loss of normal testicular function due to the size of the Leydig Cell adenomas. The secondary effects to the male reproductive organs are also not treatment related. It appears that rats are uniquely sensitive to these developmental effects and are unlikely to be relevant to humans.

Clinical indications of neurotoxicity were observed at the highest dose tested in the acute neurotoxicity study in rats. Decreased motor activity was also observed in the mid- and high-dose groups. Since the neurotoxicity was observed only at a very high dose and many of the effects are not consistent with the perturbation of the nicotinic receptor system, it is unlikely that these effects are due to activation of the nAChR.

Tumors have been observed in rat and mouse studies. In rats, there were significant increases in hepatocellular adenomas in the high-dose males. In mice, there were significant increases in hepatocellular adenomas and carcinomas in high dose males. In female mice, there was an increase in carcinomas at the high dose. Liver tumors in mice were treatment-related. Leydig cell tumors were also observed in the high-dose group of male rats, but were not related to treatment. There was also a significant increase in preputial gland tumors in male rats in the high-dose group. Given that the liver tumors are produced by a non-linear mechanism, the Leydig cell tumors were not treatment-related, and the preputial gland tumors only occurred at the high dose in one sex of one species, the evidence of carcinogenicity was weak.

#### Ecological Toxicity

Sulfoxaflor (N-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-lambda 4-sulfanylidene]) is a new variety of insecticide as a member of the sulfoxamine subclass of neonicotinoid insecticides. It is considered an agonist of the nicotinic acetylcholine receptor and exhibits excitatory responses including tremors, followed by paralysis and mortality in target insects. Sulfoxaflor consists of two diastereomers in a ratio of approximately 50:50 with each diastereomer consisting of two enantiomers. Sulfoxaflor is systemically distributed in plants when applied. The chemical acts through both contact action and ingestion and provides both rapid knockdown (symptoms are typically observed within 1-2 hours of application) and residual control (generally provides from 7 to 21 days of residual control). Incident reports submitted to EPA since approximately 1994 have been tracked via the Incident Data System. Over the 2012 growing season, a Section 18 emergency use was granted for application of sulfoxaflor to cotton in four states (MS, LA, AR, TN). No incident reports have been received in association with the use of sulfoxaflor in this situation.

Sulfoxaflor is classified as practically non-toxic on an acute exposure basis, with 96-h LC<sub>50</sub> values of >400 mg a.i./L for all three freshwater fish species tested (bluegill, rainbow trout, and common carp). Mortality was 5% or less at the highest test treatments in each of these studies. Treatment-related sublethal effects included discoloration at the highest treatment concentration (100% of fish at 400 mg a.i./L for bluegill) and fish swimming on the bottom (1 fish at 400 mg a.i./L for rainbow trout). No other treatment-related sublethal effects were reported. For an estuarine/marine sheepshead minnow, sulfoxaflor was also practically non-toxic with an LC<sub>50</sub> of 288 mg a.i./L. Sublethal effects included loss of equilibrium or lying on the bottom of aquaria at 200 and 400 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to rainbow trout on an acute exposure basis (96-h LC<sub>50</sub> >500 mg a.i./L).

Adverse effects from chronic exposure to sulfoxaflor were examined with two fish species (fathead minnow and sheepshead minnow) during early life stage toxicity tests. For fathead minnow, the 30-d NOAEC is 5 mg a.i./L based on a 30% reduction in mean fish weight relative to controls at the next highest concentration (LOAEC=10 mg a.i./L). No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and length. For sheepshead minnow, the 30-d NOAEC is 1.3 mg a.i./L based on a statistically significant reduction in mean length (3% relative to controls) at 2.5 mg a.i./L. No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and mean weight.

The acute toxicity of sulfoxaflor was evaluated for one freshwater invertebrate species, the water flea and two saltwater species (mysis shrimp and Eastern oyster). For the water flea, the 48-h EC<sub>50</sub> is >400 mg a.i./L, the highest concentration tested. For Eastern oyster, new shell growth was significantly reduced at 120 mg a.i./L (75% reduction relative to control). The 96-h EC<sub>50</sub> for shell growth is 93 mg a.i./L. No mortality occurred at any test concentration. Mysids shrimp are the most acutely sensitive invertebrate species tested with sulfoxaflor based on water column only exposures, with a 96-h LC<sub>50</sub> of 0.67 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to the water flea (EC<sub>50</sub> >240 mg a.i./L).

The chronic effects of sulfoxaflor to the water flea were determined in a semi-static system over a period of 21 days to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg a.i./L. Adult mortality, reproduction rate (number of young), length of the surviving adults, and days to first brood were used to determine the toxicity endpoints. No treatment-related effects on adult mortality or adult length were observed. The reproduction rate and days to first brood were significantly ( $p < 0.05$ ) different in the 100 mg a.i./L test group (40% reduction in mean number of offspring; 35% increase in time to first brood). No significant effects were observed on survival, growth or reproduction at the lower test concentrations. The 21-day NOAEC and LOAEC were determined to be 50 and 100 mg a.i./L, respectively.

The chronic effects of sulfoxaflor to mysids shrimp were determined in a flow-through system over a period of 28 days to nominal concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg a.i./L. Mortality of parent (F<sub>0</sub>) and first generation (F<sub>1</sub>), reproduction rate of F<sub>0</sub> (number of young), length of the surviving F<sub>0</sub> and F<sub>1</sub>, and days to first brood by F<sub>0</sub> were used to determine the toxicity endpoints. Complete F<sub>0</sub> mortality (100%) was observed at the highest test concentration of 1.0 mg a.i./L within 7 days; no treatment-related effects on F<sub>0</sub>/F<sub>1</sub> mortality, F<sub>0</sub> reproduction rate, or F<sub>0</sub>/F<sub>1</sub> length were observed at the lower test concentrations. The 28-day NOAEC and LOAEC were determined to be 0.11 mg and 0.25 mg a.i./L, respectively.

Sulfoxaflor exhibited relatively low toxicity to aquatic non-vascular plants. The most sensitive aquatic nonvascular plant is the freshwater diatom with a 96-h EC<sub>50</sub> of 81.2 mg a.i./L. Similarly, sulfoxaflor was not toxic to the freshwater vascular aquatic plant, *Lemna gibba*, up to the limit amount, as indicated by a 7-d EC<sub>50</sub> for frond count, dry weight and growth rate of >100 mg a.i./L with no significant adverse effects on these endpoints observed at any treatment concentration.

Based on an acute oral LD<sub>50</sub> of 676 mg a.i./kg bw for bobwhite quail, sulfoxaflor is considered slightly toxic to birds on an acute oral exposure basis. On a subacute, dietary exposure basis, sulfoxaflor is classified as practically nontoxic to birds, with 5-d LC<sub>50</sub> values of >5620 mg/kg-diet for mallard ducks and bobwhite quail. The NOAEL from these studies is 5620 mg/kg-diet as no treatment related mortality of sublethal effects were observed at any treatment. Similarly, the primary degradate is classified as practically nontoxic to birds on an acute oral exposure basis with a LD<sub>50</sub> of >2250 mg a.i./kg bw. In two chronic, avian reproductive toxicity studies, the 20-week NOAELs ranged from 200 mg/kg-diet (mallard, highest concentration tested) to 1000 mg/kg-diet (bobwhite quail, highest concentration tested). No treatment-related adverse effects were observed at any test treatment in these studies.

For bees, sulfoxaflor is classified as very highly toxic with acute oral and contact LD<sub>50</sub> values of 0.05 and 0.13 µg a.i./bee, respectively, for adult honey bees. For larvae, a 7-d oral LD<sub>50</sub> of >0.2 µg a.i./bee was determined (45% mortality occurred at the highest treatment of 0.2 µg a.i./bee). The primary metabolite of sulfoxaflor is practically non-toxic to the honey bee. This lack of toxicity is consistent with the cyano-substituted neonicotinoids where similar cleavage of the cyanide group appears to eliminate their insecticidal activity. The acute oral toxicity of sulfoxaflor to adult bumble bees (*Bombus terrestris*) is similar to the honey bee; whereas its acute contact toxicity is about 20X less toxic for the bumble bee. Sulfoxaflor did not demonstrate substantial residual toxicity to honey bees exposed via treated and aged alfalfa (i.e., mortality was <15% at maximum application rates).

At the application rates used (3-67% of US maximum), the direct effects of sulfoxaflor on adult forager bee mortality, flight activity and the occurrence of behavioral abnormalities is relatively short-lived, lasting 3 days or less. Direct effects are considered those that result directly from interception of spray droplets or dermal contact with foliar residues. The direct effect of sulfoxaflor on these measures at the maximum application rate in the US is presently not known. When compared to control hives, the effect of sulfoxaflor on honey bee colony strength when applied at 3-32% of the US maximum proposed rate was not apparent in most cases. When compared to hives prior to pesticide application, sulfoxaflor applied to cotton foliage up to the maximum rate proposed in the US resulted in no discernible decline in mean colony strength by 17 days after the first application. Longer-term results were not available from this study nor were concurrent controls included. For managed bees, the primary exposure routes of concern include direct contact with spray droplets, dermal contact with foliar residues, and ingestion through consumption of contaminated pollen, nectar and associated processed food provisions. Exposure of hive bees via contaminated wax is also possible. Exposure of bees through contaminated drinking water is not expected to be nearly as important as exposure through direct contact or pollen and nectar.

In summary, sulfoxaflor is slightly toxic to practically non-toxic to fish and freshwater water aquatic invertebrates on an acute exposure basis. It is also practically non-toxic to aquatic plants (vascular and non-vascular). Sulfoxaflor is highly toxic to saltwater invertebrates on an acute exposure basis. The high toxicity of sulfoxaflor to mysid shrimp and benthic aquatic insects relative to the water flea is consistent with the toxicity profile of other insecticides with similar MOAs. For birds and mammals, sulfoxaflor is classified as moderately toxic to practically non-toxic on an acute exposure basis. The

threshold for chronic toxicity (NOAEL) to birds is 200 ppm and that for mammals is 100 ppm in the diet. Sulfoxaflor did not exhibit deleterious effects to terrestrial plants at or above its proposed maximum application rates.

For bees, sulfoxaflor is classified as very highly toxic. However, if this insecticide is strictly used as directed on the Section 18 supplemental label, no significant adverse effects are expected to Louisiana wildlife. Of course, standard precautions to avoid drift and runoff to waterways of the state are warranted. As stated on the Section 3 label, risk to managed bees and native pollinators from contact with pesticide spray or residues can be minimized when applications are made before 7 am or after 7 pm or when the temperature is below 55°F at the site of application.

### **Environmental Fate**

Sulfoxaflor is a systemic insecticide which displays translaminar movement when applied to foliage. Movement of sulfoxaflor within the plant follows the direction of water transport within the plant (i.e., xylem mobile) as indicated by phosphor translocation studies in several plants. Sulfoxaflor is characterized by a water solubility ranging from 550 to 1,380 ppm. Sulfoxaflor has a low potential for volatilization from dry and wet surfaces (vapor pressure=  $1.9 \times 10^{-8}$  torr and Henry's Law constant=  $1.2 \times 10^{-11}$  atm m<sup>3</sup> mole<sup>-1</sup>, respectively at 25 °C). Partitioning coefficient of sulfoxaflor from octanol to water ( $K_{ow}$  @ 20 C & pH 7= 6; Log  $K_{ow}$  = 0.802) suggests low potential for bioaccumulation. No fish bioconcentration study was provided due to the low  $K_{ow}$ , but sulfoxaflor is not expected to bioaccumulate in aquatic systems. Furthermore, sulfoxaflor is not expected to partition into the sediment due to low  $K_{oc}$  (7-74 mL/g).

Registrants tests indicate that hydrolysis, and both aqueous and soil photolysis are not expected to be important in sulfoxaflor dissipation in the natural environment. In a hydrolysis study, the parent was shown to be stable in acidic/neutral/alkaline sterilized aqueous buffered solutions (pH values of 5, 7 and 9). In addition, parent chemical as well as its major degradate, were shown to degrade relatively slowly by aqueous photolysis in sterile and natural pond water ( $t_{1/2}$ = 261 to >1,000 days). Furthermore, sulfoxaflor was stable to photolysis on soil surfaces. Sulfoxaflor is expected to biodegrade rapidly in aerobic soil (half-lives <1 day). Under aerobic aquatic conditions, biodegradation proceeded at a more moderate rate with half-lives ranging from 37 to 88 days. Under anaerobic soil conditions, the parent compound was metabolized with half-lives of 113 to 120 days while under anaerobic aquatic conditions the chemical was more persistent with half-lives of 103 to 382 days. In contrast to its short-lived parent, the major degradate is expected to be more persistent than its parent in aerobic/anaerobic aquatic systems and some aerobic soils. In other soils, less persistence is expected due to mineralization to CO<sub>2</sub> or the formation of other minor degradates.

In field studies, sulfoxaflor has shown similar vulnerability to aerobic bio-degradation in nine out of ten terrestrial field dissipation studies on bare-ground/cropped plots (half-lives were <2 days in nine cropped/bare soils in CA, FL, ND, ON and TX and was 8 days in one bare ground soil in TX). The chemical can be characterized by very high to high mobility ( $K_{foc}$  ranged from 11-72 mL g<sup>-1</sup>). Rapid soil degradation is expected to limit chemical amounts that may potentially leach and contaminate ground water. Contamination of groundwater by sulfoxaflor will only be expected when excessive rain occurs within a short period (few days) of multiple applications in vulnerable sandy soils. Contamination of surface water by sulfoxaflor is expected to be mainly related to drift and very little due to run-off. This is because drifted sulfoxaflor that reaches aquatic systems is expected to persist while that reaching the soil system is expected to degrade quickly with slight chance for it to run-off.

When sulfoxaflor is applied foliarly on growing crops it is intercepted by the crop canopy. Data presented above appear to indicate that sulfoxaflor enters the plant and is incorporated in the plant foliage with only limited degradation. It appears that this is the main source of the insecticide sulfoxaflor that would kill sap sucking insects. This is because washed-off sulfoxaflor, that reaches the soil system, is expected to degrade.

In summary, sulfoxaflor has a low potential for volatilization from dry and wet surfaces. This chemical is characterized by a relatively higher water solubility. Partitioning coefficient of sulfoxaflor from octanol to water suggests low potential for bioaccumulation in aquatic organisms such as fish. Sulfoxaflor is resistant to hydrolysis and photolysis but transforms quickly in soils. In contrast, sulfoxaflor reaching aquatic systems by drift is expected to degrade rather slowly. Partitioning of sulfoxaflor to air is not expected to be important due to the low vapor pressure and Henry's Law constant for sulfoxaflor. Exposure in surface water results from the drifted parent compound, and only minor amounts are expected to run-off only when rainfall and/or irrigation immediately follow application. The use of this insecticide is not expected to adversely impact Louisiana ecosystems when used according to the Section 18 label. Of course, caution is needed to prevent exposure to water systems because of toxicity issues to aquatic invertebrates. As stated on the Section 3 label, this product should never be applied directly to water, to areas where surface water is present or to intertidal areas below the mean water mark. Also, the label includes the statement "Do not contaminate water when disposing of equipment rinsate."

#### **Endangered and Threatened Species in Louisiana**

No impacts are expected on endangered and threatened species by this very limited use of this insecticide as delineated in the Section 18 application. Sulfoxaflor demonstrates a very favorable ecotoxicity and fate profile as stated above and should not directly impact any protected mammal, fish, avian, or plant species. This product does adversely affect insects and aquatic invertebrates, especially bees, but the limited exposure to these species should not negatively affect endangered and threatened species in Louisiana when applications follow the label precautions.

*The above content in Section 166.20(a)(7): Discussion of Risk Information was, for the most part, prepared by Michael Hare, Ph.D. (Human Health Effects), David Villarreal, Ph.D. (Ecological Effects), and David Villarreal, Ph.D. (Environmental Fate), all with the Texas Department of Agriculture. The parts of the above content in this section, with references to Louisiana, were prepared by LDAF.*

#### **SECTION 166.20(a)(8): COORDINATION WITH OTHER AFFECTED STATE OR FEDERAL AGENCIES**

The following state/federal agencies were notified of the Louisiana Department of Agriculture and Forestry's (LDAF) actions to submit an application for a specific exemption to EPA:

- Louisiana Department of Environmental Quality (LDEQ) Water Quality
- Louisiana Department of Wildlife and Fisheries (LDWF)
- U.S. Fish and Wildlife Department

Responses from these agencies will be forwarded to EPA immediately if and when received by LDAF.

#### **SECTION 166.20(a)(9): ACKNOWLEDGEMENT BY THE REGISTRANT**

Dow AgroSciences has been notified of this agency's intent regarding this application and have offered a letter of support (Attachment 1). They have also provided a copy of the proposed Section 18 label with the use directions for this use (although this use is dependent upon approval by EPA) (Attachment 2).

#### **SECTION 166.20(a)(10): DESCRIPTION OF PROPOSED ENFORCEMENT PROGRAM**

LDAF has state statutory authority to regulate the distribution, storage, sale, use and disposal of pesticides in the state of Louisiana. LDAF will ensure proper use of the product and accurate reporting of the use information.

A final report will be submitted to EPA after the 2016 growing season for which the Section 18 specific exemption is requested. Field enforcement staff at LDAF, as appropriate, will monitor sales of Transform® WG Insecticide, make use observations, and respond to misuse complaints.

#### **SECTION 166.20(a)(11): REPEAT USES**

This is the third year LDAF has applied for this specific exemption.

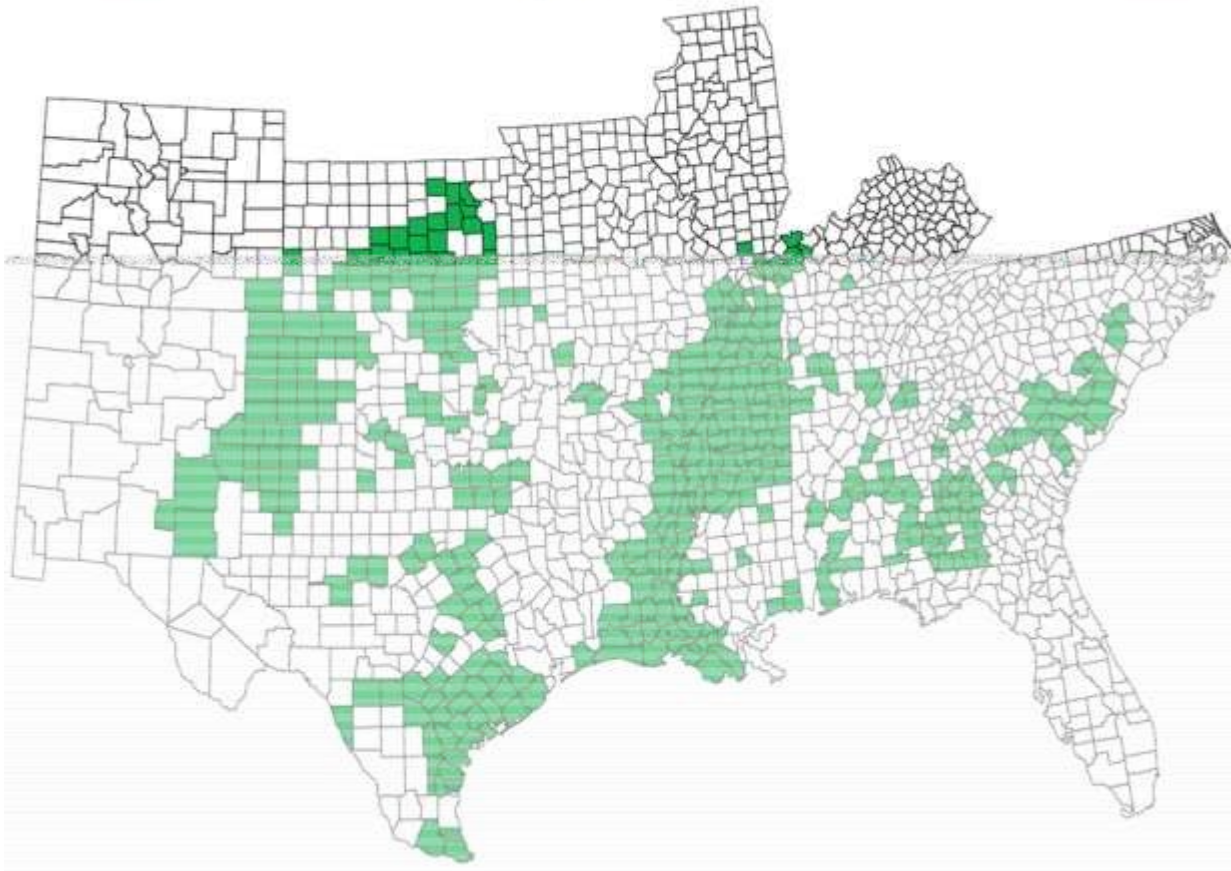
#### **SECTION 166.20(b)(1): NAME OF THE PEST**

Beginning in late-July 2013, LSU AgCenter Entomologist, Dr. David Kerns began receiving calls from farmers in Southwest Louisiana regarding difficulty in controlling aphids in grain sorghum. Based on description alone, Dr. Kerns initially thought the aphids were corn leaf aphids which are not a serious pest of sorghum. However, after viewing pictures of the aphids he realized they were most likely a different species. Shortly thereafter, a collection was made from sorghum in Rapides Parish and identified by LSU AgCenter Entomologists Drs. Julien Beuzelin and Jeff Davis as sugarcane aphid, *Melanaphis sacchari*.

This pest is most certainly *Melanaphis sacchari*, other designations such as *M. sorghi* represent synonyms. There is a recent publication that suggests that sugarcane aphids collected from sorghum in LA share a common genetic lineage with sugarcane aphids collected in HI. A comparison of sugarcane aphids from around the world, collected from a variety of host including sorghum and sugarcane suggest that all of the specimens do not greatly differ genetically based on host, but there is slight differences based on geography. The variant on sorghum may represent a biotype of *M. sacchari*, but it is definitely not a distinct species.

## **Distribution**

Below is a figure depicting distribution in the US that Dr. Bowling at TAMU has been maintaining. Dr. Kerns suspects the sugarcane aphid occurs in every Parish in LA where sorghum or sugarcane are grown and mentions it is likely present in the other parishes where Johnson grass is present.



Although the Section 18 registration of Transform proved to be highly successful, we still had a great deal to learn regarding proper management of this new pest. In 2014, sugarcane aphid infestations in Louisiana were much more severe than in 2013. We estimate that 100% of Louisiana's sorghum acreage was infested and >95% of our acres required at least one insecticide application targeting sugarcane aphid. Infestations began in the southern portions of the state in early June and quickly spread northward. By July, the entire state was infested. In the southern portion of the state most insecticide applications targeting sugarcane aphid occurred just prior to boot or at the boot stage. Applications in the northern portions of the state primarily occurred at boot, flowering and soft dough. In 2015, heavy spring rains suppressed SCA populations, and early-season infestations were not as severe as in 2014. However, along with drier conditions, in mid-July infestations were extremely common and often severe. Yield loss in 2015 was not as high as in 2014 primarily due extension efforts and growers learning better manage the pest.

**SECTION 166.20(b)(2): DISCUSSION OF EVENTS OR CIRCUMSTANCES  
WHICH BROUGHT ABOUT THE EMERGENCY SITUATION**

The events and/or circumstances which brought about the emergency situation are difficult to pinpoint. Obviously the SA shifted its host and moved into sorghum. This shift is not a large move because sugarcane and sorghum belong to the same family of grasses, Poaceae, and the genus's of *Saccharum* and *Sorghum* are closely related. The factors which brought about this shift most surely include certain weather conditions (hot, cold, wet, dry) and cropping schemes (acres planted to sugarcane, sorghum, corn, etc. The Texas A&M AgriLife Extension Service publication ENTO-035: 2/14 titled "Sugarcane Aphid: A New Pest of Sorghum" was published in the winter of 2013 (Attachment 7). Dr. David Kerns, Associate Professor of Entomology at the LSU AgCenter, contributed to this publication. This publication provides information on the current situation.

In tests LSU AgCenter and others conducted in 2014, positive yield responses were commonly noted for sugarcane aphid control in sorghum with almost exclusive use of sulfoxaflor. Although the registration of Transform proved to be highly successful, we still had a great deal to learn regarding proper management of this new pest. In 2014, sugarcane aphid infestations in Louisiana were much more severe than in 2013. We estimate that 100% of Louisiana's sorghum acreage was infested and >95% of our acres required at least one insecticide application targeting sugarcane aphid. Infestations began in the southern portions of the state in early June and quickly spread northward. By July, the entire state was infested. In the southern portion of the state most insecticide applications targeting sugarcane aphid occurred just prior to boot or at the boot stage. Applications in the northern portions of the state primarily occurred at boot, flowering and soft dough. Pyrethroid applications targeting sorghum midge (at bloom) greatly aggravated aphid populations. Where Transform was tank-mixed with pyrethroids to manage the aphid and sorghum midge, the addition of the pyrethroid appeared to sometimes negate the efficacy of Transform. Additionally, applications of Transform made under relatively cool temperatures did not perform as well as those applied under high temperatures.

Although the registration of Transform proved to be highly successful, we still had a great deal to learn regarding proper management of this new pest. In 2014, SCA infestations in Louisiana were much more severe than in 2013. In 2015, SCA infestations were not as severe, probably due to the extraordinarily wet spring we experienced in LA. However, at least 70% of our sorghum acres required treatment for this pest in 2015.

#### **SECTION 166.20(b)(3): DISCUSSION OF ANTICIPATED RISKS TO ENDANGERED OR THREATENED SPECIES, BENEFICIAL ORGANISMS, OR THE ENVIRONMENT REMEDIED BY THE PROPOSED USE**

Since the efficacy of the insecticides currently registered for the control of aphids on sorghum is poor, growers will be forced to use the maximum rates and may 'over-apply' to gain control. The utilization of high application rates can negatively impact beneficial insects and other organisms, possibly exasperating SA infestations and spurring outbreaks of secondary pests. Also, these higher use rates have the potential to negatively impact non-target organisms.

#### **SECTION 166.20(b)(4): DISCUSSION OF SIGNIFICANT ECONOMIC LOSS**

Over the past three years sorghum producers, in Louisiana, have had to contend with highly damaging populations of sugarcane aphid (SCA), *Melanaphis sacchari*. The SCA is a unique pest in that it can potentially damage sorghum from the time it emerges until harvest. Seedling sorghum may be stunted or outright killed by SCA, sorghum during panicle development may be stunted or rendered sterile and sorghum during grain filling will suffer reduced seed weight. Furthermore, potentially severe problems may arise after grain is mature. SCA excretes copious amounts of honeydew which renders the leaves sticky. When combines attempt to process these leaves the sticky materials clog the screens allowing most of the grain to be expelled from the rear of the machine. Combines that clog have to be thoroughly cleaned with pressure washers before they can resume harvest. Additionally, the honeydew covers belts and pulleys making them slick, resulting in belts prematurely failing. If left unabated, the economic losses associated with this pest are extremely high, making grain sorghum production a money losing venture.

Based on a survey of Louisiana sorghum growers, individual crop damage due to SA infestations (grower estimates) varied widely from 5% to 100% yield loss in infested fields. Grower survey data were tabulated and summarized by Dr. Kurt Guidry (Attachment 5). Using the information provided by Dr. Guidry, both Tier 1 and Tier 3 criteria have been met, demonstrating significant economic loss to sorghum by SA in Louisiana in 2013.

In tests the LSU AgCenter and others conducted in 2014, positive yield responses were commonly noted for sugarcane aphid control in sorghum. On one such test treated at bloom, 100 sugarcane aphids per leaf were demonstrated to result in 340 lbs of grain yield loss. It is not uncommon for aphids to number 1000's per leaf. In another test, 100 aphids resulted in 578 lbs of grain loss. In addition to bloom, yield loss due to aphid infestations has also been demonstrated at the seedling stage, pre-boot, boot, milk and soft dough stages. Although direct yield loss is not known to occur at hard dough stage, harvest efficiency issues where aphids and sticky leaves clog the combine have resulted in as much as 50% grain loss. Because of this loss at harvest, growers are in need of an insecticide that can be utilized at harvest with a 3 day or less PHI. This product does not currently exist.